

**Program Announcement**  
**for the**  
**Department of Defense**  
**Congressionally Directed Medical Research Programs**

**Parkinson's Research Program**  
**Impact Award**

**Funding Opportunity Number: W81XWH-16-PRP-IA**  
**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical**  
**Research and Development**

**SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), September 7, 2016
- **Invitation to Submit an Application:** October 19, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, November 30, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, December 7, 2016
- **Peer Review:** February 2017
- **Programmatic Review:** March 2017

*This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications to the Fiscal Year 2016 (FY16) Parkinson's Research Program (PRP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA). The executing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP).

The PRP (formerly the Neurotoxin Exposure Treatment Parkinson's Research Program) was initiated in FY97 to provide support for research of exceptional scientific merit leading to an understanding of the cause, prevention, and treatment of the loss of dopaminergic neurons in the substantia nigra that results in Parkinson's disease. Appropriations for the PRP from FY97 through FY15 totaled \$388.75 million (M). The FY16 appropriation is \$16M.

The PRP challenges the scientific community to develop the most impactful research that will advance the understanding of and ultimately end Parkinson's disease.

The vision of the PRP is to slow the progression of, prevent, and cure Parkinson's disease in order to lessen personal and societal impact of the disorder.

### **B. FY16 PRP Impact Award Focus Areas**

***All applications to the FY16 PRP Impact Award Program Announcement/Funding Opportunity MUST address at least one of the following FY16 PRP Impact Award Focus Areas:***

- Studies of the neurovascular unit (including neurons, glia, the microvasculature, and the blood-brain barrier) in Parkinson's disease and changes associated with its treatment.
- Identification and evaluation of mechanisms in early Parkinson's disease involving olfactory, microbiome, gastrointestinal, and/or autonomic nervous systems.
- Mechanisms of neuroplasticity and compensation in Parkinson's disease, such as influences of sleep, exercise, and diet.
- Underlying factors influencing Parkinson's disease progression in specific community-based populations (e.g., Veterans) to identify heterogeneity.

### **C. Award Information**

The PRP Impact Award mechanism is being offered for the first time in FY16.

The Impact Award encourages applications that support the full spectrum of research projects or ideas that specifically focus on scientific and clinical Parkinson's disease issues, which, if successfully addressed, have the potential to make a major impact in preventing or halting the progression of Parkinson's disease or enhancing the well-being of individuals experiencing the impact of the disease.

The PRP seeks applications from investigators from a spectrum of disciplines including, but not limited to, basic science, engineering, bioinformatics, population science, translational research, and clinical research, **NOT** including clinical trials. Projects that incorporate population science-based approaches are particularly encouraged. The critical components of this award mechanism are:

- **Impact:** The Impact Award is intended to support research that demonstrates the potential to have a major impact on an area of paramount importance in Parkinson's disease. It is the responsibility of the Principal Investigator (PI) to clearly and explicitly describe the potential impact of the proposed study on Parkinson's disease and to convey its level of significance. The research impact is intended to benefit individuals with Parkinson's disease including Service members and Veterans by slowing the progression of, preventing, and/or curing Parkinson's disease.
- **Focus Area:** *The proposed research MUST address at least one of the FY16 PRP Impact Award Focus Areas.*
- **Research Approach:** The scientific rationale and experimental methodology should demonstrate critical understanding and in-depth analysis of Parkinson's disease. Experimental strategies may be novel or may be based on strong rationale derived from previously published data, presented preliminary data, or literature review. The feasibility of the research design and methods should be well defined, and a clear plan should be articulated as to how the proposed goals of the project can be achieved.  
*Preliminary data are required.* Any unpublished, preliminary data provided should originate from the laboratory of the PI or a member(s) of the research team. The preliminary data must support the feasibility of the study.
- **Principal Investigator and Research Team:** The FY16 PRP Impact Award seeks applications from investigators from a spectrum of disciplines including, but not limited to, basic science, engineering, bioinformatics, population science, translational research, and clinical research. The application should demonstrate that the research team's background is appropriate to successfully achieve the proposed research and contribute to the field of Parkinson's disease research.

**Data and Research Resources Sharing Plan:** It is the intent of the Impact Award that data and research resources generated by funded research activities will be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. Each application should include a data and/or research resources sharing plan describing how unique and/or final research data will be shared, along with any resulting research resources. This information should be provided as the Data and Research Resources Sharing Plan as described in [Section II.C., Full Application Submission Content](#), of this Program Announcement/Funding Opportunity. Refer also to the General Application Instructions, Appendix 4, for more information.

**Partnering PI Option:** The Impact Award mechanism includes an option for up to three PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) (*Maximum of two*) will be identified as a Partnering PI(s). Initiating and Partnering PIs each have different submission requirements, as described in Section II, Submission Information; however, all PIs

should contribute significantly to the development of the proposed research project. If recommended for funding, each PI will receive his or her own award. ***To justify the higher funding level, the research project must be supported by the unique expertise, experience, and abilities of each PI, and the application must clearly define the synergistic components that will facilitate and accelerate progress in a way that could not be accomplished through independent efforts.*** Multidisciplinary projects are encouraged, and multi-institutional projects are allowed. Each proposed study must include clearly stated plans for interactions among all PIs and organizations involved. The plans must include communication, coordination of research progress and results, and data transfer. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

***Research involving human subjects and human anatomical substances is permitted; however, clinical trials are not allowed under this Program Announcement/Funding Opportunity.*** A clinical trial is defined as a prospective accrual of patients in which an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction. For more information on clinical trials and clinical research overall, a Human Subject Resource Document is provided on the CDMRP electronic Biomedical Research Application Portal (eBRAP) system at (<https://ebrap.org/eBRAP/public/Program.htm>).

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) for additional information.

**Rigor of Experimental Design:** All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in Landis, S.C., et al. A call for transparent reporting to optimize the predictive value of preclinical research, *Nature* 2012, 490:187-191 ([www.nature.com/nature/journal/v490/n7419/full/nature11556.html](http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html)). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Applicants should consult the

ARRIVE (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at [http://www.elsevier.com/\\_data/promis\\_misc/622936arrive\\_guidelines.pdf](http://www.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf).

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

**Use of Military and VA Populations or Resources:** If applicable, access to target military or Department of Veterans Affairs (VA) patient population(s) or resources should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included in Attachment 2 for studies involving active duty military, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.

***The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.***

#### **D. Eligibility Information**

- Independent investigators at or above the level of Assistant Professor (or equivalent) are eligible to submit an application.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. ***If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator’s Commander or***

***Commanding Officer at the intramural organization that authorizes the collaborator's involvement.***

- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

## **E. Funding**

### **Single PI:**

- The maximum period of performance is **4** years.
- The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **\$3M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$3M** total costs or using an indirect rate exceeding the organization's negotiated rate.

### **Partnering PI Option:**

- The maximum period of performance is **4** years.
- The anticipated combined total costs budgeted for the entire period of performance for the Initiating PI and the Partnering PI's/PIs' applications will not exceed **\$5M**. The combined total costs of Initiating PI and the Partnering PI's/PIs' awards will not exceed **\$5M**. If the Initiating PI's or Partnering PI's/PIs' budgets contain a subaward (or multiple subawards), all costs of the subaward(s) must be included in the total costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted total costs (direct and indirect) approved by the Government will not exceed **\$5M** or use an indirect rate exceeding each organization's negotiated rate.
- A separate award will be made to each PI's organization.
- The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly, unless otherwise warranted and clearly justified.

### **For both the Single PI and the Partnering PI Option:**

- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant(s) may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Clinical research costs
- Equipment

- Support for multidisciplinary collaborations, including travel
- Travel costs for up to two investigator(s) to travel to one scientific/technical meeting per year.

Shall not be requested for:

- Clinical trial costs.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

***The CDMRP expects to allot approximately \$11M of the \$16M FY16 appropriation(s) to fund approximately three Impact Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.***

## II. SUBMISSION INFORMATION

***Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).***

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application



submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

***The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507 prior to the application deadline.***

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

**Partnering PI Option:** The Impact Award mechanism is structured to accommodate up to three PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI(s) (***Maximum of two***) will be identified as Partnering PI(s). Initiating and Partnering PIs each have different submission requirements; however, all PIs should contribute significantly to the development of the proposed research project including the Project Narrative, Statement of Work, and other required components. The Initiating PI must complete the pre-application submission process and submit the contact information for each Partnering PI. Each Partnering PI will then be notified of the pre-application submission separately by email. ***Each Partnering PI must follow the link in this email in order to associate his/her Grants.gov application package with that of the Initiating PI.*** If not previously registered, a Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by a Partnering PI. Do not delay completing these steps. If they are not completed, the Partnering PI(s) will not be able to view and modify his/her application during the verification period in eBRAP.

#### **A. Where to Obtain the Grants.gov Application Package**

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-PRP-IA in Grants.gov (<http://www.grants.gov/>).

#### **B. Pre-Application Submission Content**

***The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.***

All pre-application components must be submitted by the Initiating PI through eBRAP (<https://eBRAP.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Tab 3 – Collaborators and Key Personnel**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - [FY16 PRP Programmatic Panel members](#) should not be involved in any pre-application or application. For questions related to Panel members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.
  - **Partnering PI Option:** The Initiating PI must enter the contact information for each Partnering PI (*maximum of two*) in the Partnering PI section.

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess.shtml>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**

- List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

*Note: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*

**Preproposal Narrative (three-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Background/Rationale:** Present the ideas and reasoning behind the proposed research, to include relevant literature citations.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Approach:** State the project's specific aims and briefly describe the experimental approach to accomplishing the aims. Describe the preliminary power analysis that reflects sample size projections that will address the hypothesis and/or objective(s) of the proposed project (if applicable). Describe the availability of the necessary research resources as determined by the preliminary power analysis, and a brief summary of the plan for acquiring these research resources.
- **Relevance:** State how the project is responsive to at least one of the FY16 PRP Impact Award Focus Areas.
- **Principal Investigator and Research Team:** Describe the composition, expertise and organization of the research team and each team member's role in the project(s). Briefly describe how these features will facilitate the success of the key

aspects the project(s). Include evidence of sufficient clinical and/or statistical expertise, if applicable.

- **Partnering PI Option (if applicable):** Identify the Initiating and Partnering PI(s) and describe the expertise each will bring to the project. Describe how the combined expertise and efforts will provide synergy and enhance the research effort to produce an outcome greater than any that could be achieved by independent efforts. Include a description of how the combined efforts are centered on a unified objective and how the PIs will work together to achieve that objective from different perspectives.
- **Impact:** Describe the intended outcome of the proposed research and how it will make a *major impact* in slowing the progression of, preventing, and/or curing Parkinson's disease.

**Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual files* and are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- **Key Personnel Biographical Sketches (five-page limit per individual).** *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

- This tab must be completed for the pre-application to be accepted and processed.

## **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the PRP, pre-applications will be screened based on the following criteria:

- **Intent of the Award Mechanism:** To what degree the proposed research project addresses at least one of the FY16 PRP Impact Award Focus Areas, as well as has potential to make a major impact in slowing the progression of, preventing, and/or curing Parkinson's disease.
- **Research Approach:** How well the rationale and specific aims support the project's objective(s). How the necessary research resources, as determined by the preliminary power analysis, are available to and accessible by the PI(s).

- **Principal Investigator and Research Team:** To what degree the research team's background is appropriate with respect to its ability to successfully complete the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise, if applicable.
- **Synergy (*Partnering PI Option Only*):** How well the proposed study represents a synergistic collaboration that will produce results greater than what could be accomplished through individual efforts. To what degree it is evident that all PIs have provided appropriate levels of intellectual input into the proposed project.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs or Initiating PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

### C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

***Applications will not be accepted unless the PI or Initiating PI has received notification of invitation.***

***All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.***

***The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

Each application submission must include the completed Grants.gov application package for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

***Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.***

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be

submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

**Partnering PI Option:** The CDMRP requires separate Grants.gov application package submissions for the Initiating PI and each Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each Grants.gov application package must be submitted using the unique eBRAP log number. *Note: All associated applications (Initiating and each Partnering PI) must be submitted by the Grants.gov deadline.*

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

<b>Application Components for Single PIs or for the Initiating PI under the Partnering PI Option:</b>
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**Grants.gov application package components:** For the Impact Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (15-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background/Rationale:** Briefly describe the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. Demonstrate logical reasoning and provide a

sound scientific rationale for the proposed project as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept and clinical relevance.

- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project's specific aims to be funded by this award.
- **Research Strategy:** Describe the experimental design, methods, and analyses including appropriate controls and endpoints to be tested (if applicable) in sufficient detail for analysis.
  - Explain how this research strategy will meet the research goals and milestones. Address potential pitfalls and problem areas and present alternative methods and approaches.
  - Clearly identify the source of any proposed cell lines, and whether they were recently authenticated and/or tested for mycoplasma contamination, if applicable.
  - If the methodology is new or unusual, provide sufficient details for evaluation.
  - Describe the availability of the necessary resources, including human subjects or human anatomical samples; include a detailed plan for the recruitment of subjects or the acquisition of samples. Address any potential ethical concerns. Outline how approvals from local IRBs will be obtained and how the informed consent process will be initiated, as applicable.
  - Describe the statistical plan including power analysis that reflects sample size projections that will address the hypothesis and/or the objectives of the project. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines ([http://www.elsevier.com/data/promis\\_misc/622936arrive\\_guidelines.pdf](http://www.elsevier.com/data/promis_misc/622936arrive_guidelines.pdf)).
  - Describe how the clinical relevance of the anticipated findings will be determined, if applicable.
  - Provide an overall strategic plan for completing the proposed project. If the entire project will not be completed during the performance period of the award (i.e., requires longitudinal follow-up), provide evidence that sufficient funds will be available to complete the project.
- **Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf."** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will***



***result in the removal of those items or may result in administrative withdrawal of the application.***

- References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- Letters of Collaboration: Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.



- Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section K for more information about the CDMRP expectations for making data and research resources publicly available.
- Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Describe the proposed research project including the following elements:

- **Background:** Present the ideas and reasoning behind the proposed project.
  - **Relevance:** State which of the FY16 PRP Impact Award Focus Area(s) will be addressed.
  - **Hypothesis (or Objective):** State the hypothesis (or hypotheses) to be tested or the objective to be reached.
  - **Specific Aims:** State the specific aims of the study.
  - **Research Strategy:** Briefly describe the research strategy to include methodology, statistical analysis, and appropriate controls.
  - **Impact:** Summarize the impact of the proposed research, if successful, on slowing the progression of, preventing, and/or curing Parkinson’s disease
- **Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The lay abstract is used by all reviewers. Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to the consumer community.

- Clearly describe, in a manner readily understood by readers without a background in science or medicine, the rationale, objective, and aims of the application.
- Do not duplicate the technical abstract.
- Describe the relationship of the proposed work to the specific Focus Area(s) of this Program Announcement/Funding Opportunity.
- Describe the ultimate applicability of the research.
  - What types of patients will it help and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected time it may take to achieve a patient-related outcome?
  - What is the likely impact of this study on slowing the progression of, preventing, and/or curing Parkinson's disease
- **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as "SOW.pdf."** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>). For the Impact Award mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

**Partnering PI Option:** Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task. For investigators applying under this option, PIs are encouraged to use the SOW format example titled "SOW for Collaborative PI projects."
- **Attachment 6: Relevance Statement (one-page limit): Upload as "Relevance.pdf."** Describe how the proposed research will directly address at least one of the FY16 PRP Impact Award Focus Areas.
- **Attachment 7: Impact Statement (one-page limit): Upload as "Impact.pdf."** Articulate the pathway to making a clinical impact for individuals with, or at risk for, Parkinson's disease. Describe the near-term impact as well as the long-term impact. The near-term impact will be anticipated outcome(s)/product(s) from the proposed research. The long-term impact may be beyond the scope of the proposed research.
- **Attachment 8: Research Team Statement (one-page limit): Upload as "Team.pdf."** Discuss the qualifications of the research team, each individual's

specific contributions to the project, including how the appropriate expertise is incorporated to address the research question and enable the success of the proposed project.

- **Attachment 9: Synergy Statement (two-page limit): Upload as “Synergy.pdf.”** (*Attachment 9 is only applicable and required for applications submitted under the Partnering PI Option.*)
  - Discuss in detail the advantages of addressing this problem through the combined expertise of the PIs and how this contributes to the synergy of the application. Include each PI’s history of synergistic and collaborative study with one another and/or with other investigators.
  - Describe the elements of interdependence in the proposed work and the contributions of each PI to the overall synergy of the project. Describe how the combined efforts of the PIs will result in a level of productivity that is greater than that achievable by each PI working independently.
  - Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all PIs and organizations participating in the project.
- **Attachment 10: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information.

- **PI Biographical Sketch (five-page limit): Upload as “Biosketch\_LastName.pdf.”** The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- **PI Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”**

- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch\_LastName.pdf.”
    - Include biographical sketches for the Partnering PI(s), if applying under the Partnering PI Option.
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
    - Include previous/current/pending support for the Partnering PI(s), if applying under the Partnering PI Option.
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- **Budget Justification (no page limit):** Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
  - **Partnering PI Option:** Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Initiating PI should not include budget information for Partnering PI(s), even if they are located within the same organization. The anticipated combined total costs (direct and indirect) budgeted for the entire period of performance for the Initiating PI and the Partnering PI’s/Pis’ applications will not exceed \$5M. If the Initiating PI’s or Partnering PI’s/Pis’ budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate. The combined budgeted total costs approved by the Government will not exceed \$5M or using an indirect rate exceeding each organization’s negotiated rate.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 10, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

<b>Application Components for the Partnering PI(s):</b>
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Each Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate his/her Grants.gov application package with that of the Initiating PI.

The application submission process for Partnering PI(s) uses an abbreviated Grants.gov application package that includes:

- 1. SF424 (R&R) Application for Federal Assistance Form**
- 2. Attachments Form**
  - **Attachment 5: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** Refer to the General Application Instructions, Section II.C.2., for detailed information on completing the SOW. *Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and Partnering PI(s) should be noted for each task.*
- 3. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
  - **Budget Justification** (no page limit): Upload as “**BudgetJustification.pdf.**”
  - **Partnering PI Option:** Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov application packages. The Research & Related Budget for the Partnering PI(s) should not include budget information for the Initiating PI, even if they are at the same organization. The anticipated combined total costs (direct and indirect) budgeted for the entire period of performance for the Initiating PI and the Partnering PI’s/PIs’ applications will not exceed \$5M. If the Initiating PI’s or Partnering PI’s/PIs’ budgets contain a subaward (or multiple subawards), all direct and indirect costs of the subaward(s) must be included in the direct costs of the primary award. Collaborating organizations should budget associated indirect costs in accordance with each organization’s negotiated rate. The combined budgeted total costs approved by the Government will not exceed \$5M or using an indirect rate exceeding each organization’s negotiated rate.
- 4. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 5. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.5., for detailed information.

Collaborating DoD Military Facilities Form: Refer to the General Application Instructions, Section II.C.7., for detailed information. The costs per year should be included on the Grants.Gov Research and Related Budget form under subaward costs.

#### **D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

#### **E. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

#### **F. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

### **III. APPLICATION REVIEW INFORMATION**

#### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General of the USAMRMC, based on technical merit, the relevance to the mission of the PRP, to the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not***

*automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2., Programmatic Review](#).* Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

## **B. Application Review Process**

**1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

- **Impact**
  - How the proposed research, if successful, will contribute to a pathway toward making a clinical impact for individuals with, or at risk for, Parkinson's disease.
  - To what degree the proposed research, whether in the near-term or long-term, would make a major impact in slowing the progression of, preventing, and/or curing Parkinson's disease.
- **Relevance**
  - How well the proposed research addresses one or more of the FY16 PRP Impact Award Focus Areas.
- **Research Strategy and Feasibility**
  - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data, and logical reasoning.
  - How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
  - To what extent the proposed research project is feasible as described.
  - How well the PI acknowledges potential problems and addresses alternative approaches.
  - Whether the application includes an appropriate statistical plan with power analysis (if applicable).

- Whether the PI has provided sufficient evidence to support availability of and access to the populations/samples required for the study, and whether the plan for acquiring the necessary research resources is sufficient for the proposed research project (if applicable).
- How well the animal study (or studies) is designed to achieve the objectives and generate reproducible and rigorous results (if applicable).
- Whether experiments to address the clinical relevance of the anticipated findings have been incorporated into the study design (if applicable).
- Whether appropriate measures have been taken or are in place to authenticate proposed cell lines and/or test for mycoplasma contamination (if applicable).
- Whether the PI has provided sufficient evidence that resources will be available to complete longitudinal follow-up beyond the period of performance (if applicable).
- **Principal Investigator and Research Team**
  - To what degree the research team's background is appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient clinical and/or statistical expertise (if applicable).
  - How the levels of effort are appropriate for successful conduct of the proposed work.
- **Synergy (*Partnering PI Option only*)**
  - How the proposed partnership between/among the PIs is likely to result in a level of productivity that is greater than that achievable by each PI working independently.
  - To what degree the contributions of each PI to the project are appropriate and balanced.
  - How well the application addresses processes for ongoing communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all participating PIs and organizations.

In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Data and Resource Sharing**
  - To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider Parkinson's disease research community.
- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.



- **Application Presentation**

- To what extent the writing, clarity, and presentation of the application components influence the review.

- **Environment**

- To what degree the scientific environment is appropriate for the proposed research.
- How well the research requirements are supported by the availability of and access to facilities and resources (including patient populations, samples, and collaborative arrangements).
- To what degree the quality and extent of institutional support are appropriate for the proposed research.
- If applicable, to what degree the intellectual and material property plan is appropriate.

**2. Programmatic Review:** To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

**a. Ratings and evaluations of the peer reviewers**

**b. Relevance to Congressional intent and the vision of PRP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio balance
- Programmatic relevance to the FY16 PRP Impact Award Focus Areas
- Relative impact

## **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

## **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity.

## **E. Notification of Application Review Results**

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the application.

## IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

### A. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.
- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.
- Partnering PI Option: All associated [Initiating and Partnering PI(s)] applications are not submitted by the deadline.

### B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

### C. Withdrawal

The following may result in administrative withdrawal of the pre-application or application:

- An FY16 PRP Programmatic Panel member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY16 PRP Programmatic Panel members can be found at <http://cdmrp.army.mil/prp/panels/panels16.shtml>.*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess.shtml>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- All associated [Initiating and Partnering PI(s)] applications are not submitted by the deadline.
- The invited application does not propose the same research project described in the pre-application.
- If a clinical trial is proposed, the application will be withdrawn.
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

#### **D. Withhold**

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the application.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

## **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

## **C. National Policy Requirements**

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

## **D. Reporting**

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements. Quarterly technical progress reports and quad charts will be required. In addition to written progress reports, in-person presentations may be requested.

If employing the Partnering PI Option, each PI, whether the Initiating or a Partnering PI, must submit individual progress reports as required by his/her individual award agreement.

## **E. Award Transfers**

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

**Partnering PI Option:** An organizational transfer of an award supporting the Initiating or Partnering PI is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

# **VI. VERSION CODES AND AGENCY CONTACTS**

## **A. Program Announcement/Funding Opportunity and General Application Instructions Version**

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code 20160210j. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code 20160210.

## **B. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

## **C. Grants.gov Contact Center**

Questions related to application submission through Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726; International 1-606-545-5035

Email: [support@grants.gov](mailto:support@grants.gov)

***Sign up on Grants.gov for “send me change notification emails” by following the link on the Synopsis page for the Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.***

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Initiating PI Completed	Partnering PI Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.		
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."		
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."		
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."		
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."		
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."		
	6	Relevance Statement: Upload as Attachment 6 with file name "Relevance.pdf."		
	7	Impact Statement: Upload as Attachment 7 with file name "Impact.pdf."		
	8	Research Team Statement: Upload as Attachment 8 with file name "Team.pdf."		
	9	Synergy Statement ( <i>required for Partnering PI Option only</i> ): Upload as Attachment 9 with file name "Synergy.pdf," if applicable.		
	10	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf," if applicable.		
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.		
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.		
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.		
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.		
Research & Related Budget		Complete form as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.		
Project/Performance Site Location(s) Form		Complete form as instructed.		
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.		